DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

D1099B

January 15, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 28

Terrand B. Grall, Ph.D.
President,
Consumer Care Products, Inc.
810 North Water Street
Sheboygan, Wisconsin 53082

Dear Dr. Grall:

During an inspection of your firm located in Sheboygan, WI, on January 7, 1997, our investigator determined that your firm manufactures physical medicine devices: miniature pressure transducers, prosthetic and orthotic accessories, mechanical chairs, mechanical tables, mechanical walkers, wheelchair accessories and components, and non-measuring exercise equipment. These items are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that your devices are misbranded within the meaning of Section 502(o) of the Act in that they are being manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under Section 510, and was not included in a list required by Section 510(j).

Our records show that you were informed of this deficiency during the previous inspections of your firm on January 15, 1985, and November 10, 1992. To date we have no record of your firm's registration or listing of your products as required by the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612) 334-4100 ext. 156.

Enclosed are instructions and forms for you to complete in order to register your firm and list your products. You may contact the Division of Small Manufacturer's Assistance toll free at 1-800-638-2041 if you need help in this or any other device-related areas.

Sincerely yours,

John Feldman
Director
Minneapolis District

HEM/ccl

Enclosures: Device and Establishment registration
forms and instructions